

OTC DRUG REVIEW INGREDIENT STATUS REPORT

September 1, 1994**

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The alphabetical listing of ingredients reflects the status of the individual active ingredients in the OTC Drug Review as published in the FEDERAL REGISTER. It is important to note that the current status may be different based upon the agency's feedback policy described in the FEDERAL REGISTER of September 29, 1981 (46 FR 47740). A public record of information is available in the Dockets Management Branch under Docket No. 80N-0295.

The following headings are used on each page and are explained below.

INGREDIENT

The ingredient names are listed in accordance with the "USAN and USP Dictionary of Drug Names." Ingredients not identified in the "USAN and USP Dictionary of Drug Names" are also included and listed as the common names preferred by the agency for these ingredients. In some cases, the Panels reviewed ingredients as a general class rather than as a single entity. Where this occurred, the general class is shown rather than the individual ingredient.

See pages 6 through 14 for listing of ingredient name changes and ingredient name additions.

**This will be updated in the near future.

PANEL ASSOCIATION

The following is an index to the OTC Advisory Review Panels used throughout the ingredient list.

AN	ANTACID
AP	ANTIPERSPIRANT
A1	ANTIMICROBIAL I
A2	ANTIMICROBIAL II
CC	COUGH/COLD
CV	CONTRACEPTIVE/VAGINAL
DN	DENTAL
HM	HEMORRHOIDAL
IA	INTERNAL ANALGESIC
LX	LAXATIVE
ME	MISCELLANEOUS EXTERNAL
MI	MISCELLANEOUS INTERNAL
NA	NOT APPLICABLE
OC	ORAL CAVITY
O	OPHTHALMIC
SS	SEDATIVE
TA	TOPICAL ANALGESIC

REPORT NAME

The following is an index to the codes of OTC drug review reports used throughout the ingredients list.

AA	ANTACID
AB	ANTIBIOTIC
AC	ANTICARIES
AD	ANTIDIARRHEAL
AE	ANTIEMETIC
AF	ANTIFUNGAL
AH	ANTHELMINTIC
AK	ACNE
AL	ALCOHOLS (TOPICAL)
AM	ANTIMICROBIAL
AN	ANTIFLATULENT
AP	ANTIPERSPIRANT
AR	ANORECTAL
AS	ASTRINGENT
AT	ACUTE TOXIC INGESTION
AX	APHRODISIAC
BT	BOIL TREATMENT
BP	BENIGN PROSTATIC HYPERTROPHY
CA	COUGH COLD (ANTICHOLINERGIC)
CB	COUGH COLD (BRONCHODILATOR)
CC	COUGH COLD (COMBINATIONS)
CE	COUGH COLD (EXPECTORANT)
CG	COUGH COLD (GENERAL)
CH	COUGH COLD (ANTIHISTAMINE)
CK	CHOLECYSTOKINETIC
CN	COUGH COLD (NASAL DECONGESTANT)
CO	CAMPHORATED OIL
CR	CORN/CALLUS REMOVER
CS	CAMPHOR STATEMENT
CT	COUGH COLD (ANTITUSSIVE)
CV	CONTRACEPTIVE (VAGINAL)
DA	DIGESTIVE AID
DE	DEODORANTS FOR INTERNAL USE
DH	DIPHENHYDRAMINE NOTICE

DP	DANDRUFF/SEBORRHEIC DERMATITIS/PSORIASIS
DR	DIAPER RASH
DS	DAYTIME SEDATIVE
EA	EXTERNAL ANALGESIC
EM	EMETIC
EP	EXOCRINE PANCREATIC INSUFFICIENCY
FB	ORAL DRUGS FOR FEVER BLISTER
FE	FEVER BLISTER/COLD SORE (EXTERNAL)
HG	HAIR GROWER/LOSS
HO	HORMONE
HY	HYPOPHOSPHATEMIA/HYPERPHOSPHATEMIA
IA	INTERNAL ANALGESIC
IB	INSECT BITE & STING
IO	ORAL INSECT REPELLENT
IR	INSECT REPELLENT
IT	INGROWN TOENAIL
LC	LEG MUSCLE CRAMPS
LX	LAXATIVE
MD	MENSTRUAL/DIURETIC
ME	MERCURY
MG	MALE GENITAL DESENSITIZER
NS	NIGHTTIME SLEEP-AID
NT	NAILBITING/THUMBSUCKING
OD	RELIEF OF ORAL DISCOMFORT
OH	ORAL HEALTH CARE
OI	ORAL MUSCOSA INJURY
O	OPHTHALMIC
OR	OVERINDULGENCE IN ALCOHOL AND FOOD
OT	OTIC
PE	PEDICULICIDE
PI	POISON IVY/OAK/SUMAC PREVENTION
PT	POISON TREATMENT
PW	PREGNANCY WARNING
SA	STOMACH ACIDIFIER
SB	SKIN BLEACHING
SD	SMOKING DETERRENT
SK	SKIN PROTECTANT

SN	SWEET SPIRITS OF NITRE
ST	STIMULANT
SU	SUNSCREEN
TR	TRICLOSAN
VG	VAGINAL
WC	WEIGHT CONTROL
WR	WART REMOVER

PHARMACEUTICAL USE

The specific pharmacologic or therapeutic class (i.e., indication for use) of the ingredient being categorized is identified in this column.

CATEGORIZATION COLUMN

Adopted Report (ANPR) - the agency has published the unaltered conclusions and recommendations of the particular OTC Advisory Review Panel charged with the review of these ingredients as an Advance Notice of Proposed Rulemaking (ANPR). This publication was designed to stimulate discussion, evaluation, and comment on the full sweep of the Panel's deliberations. The Panel's report was prepared independently of FDA and represents the best scientific judgment of the panel members, but did not necessarily reflect the agency's position on any particular matter contained in it.

Proposed Rule (FDA) - the agency has evaluated the Panel's report and the comments received in response to the ANPR and has published a Proposed Rule (PR) which contains a tentative final monograph or regulation for the specific OTC drug product(s) under review. This document represents the agency's position and proposal on this issue.

Final Rule (FDA) - the agency has evaluated comments received in response to the PR and has published a Final Rule (FR) which contains a final monograph or regulation for the specific OTC drug product(s) under review. This document constitutes final agency action on the issue.

CATEGORIES

Category I - conditions under which OTC drug products are generally recognized as safe and effective and are not misbranded.

Category II - conditions under which OTC drug products are not generally recognized as safe and effective or are misbranded.

Category III - conditions for which the available data are insufficient to permit final classification at this time as Category I or II.

For categories II and III the reason for the categorization is symbolized by S (safety) and/or E (effectiveness).

If a categorization column is blank for any particular ingredient, that ingredient has not yet been categorized for the indicated document. If N/A is shown, then that ingredient was either not classified by the Panel or was not included in the indicated document. If ND is shown, then that ingredient has been determined to be a new drug. TRA means transferred, DEF means deferred, and PL means professional labeling.

*Amendment for Final Monograph 54FR8320, February 28, 1989, classified as Category I.

**Danthron as a stimulant laxative; drug recall letter declared ingredient a new drug.

INGREDIENT NAME CHANGES

The following listing is provided to assist location of those ingredients which are listed under a different name or format in this edition than that listed for the same ingredients in the January 1984, August 1985, November 1986, January 1988, or April 1989 editions of the Ingredient Status Report.

JANUARY 1984 EDITION

8-Hydroxyquinoline
Acetanilid
Alcohol 14 percent
Alkaloids of Sabadilla
Alkyldimethyl Benzylammonium Chloride
Alum
Alum Ammonium
Alum (Powdered Alum)
Aluminum Carbonate (Gel)
Aluminum Dihydroxy Allantoinate
Aluminum Hydroxide (Gel)
Aluminum Phosphate (Gel)
Aluminum Zirconium Tetrachlorohydrate Glycine Complex
Aluminum Zirconium Trichlorohydrate Glycine Complex
Aminoacetic acid
Aminoacridine Hydrochloride
Ammonium Alum
Amyltriethylol, Secondary
Amyl Dimethyl-p-Aminobenzoate
Amyl Para-Dimethylaminobenzoate
Amylum
Aqua Ammonia
Aqueous Coconut Oil Soap
Balsam Peru
Balsam Peru Oil
Bicarbonate of Soda
Borax
Bran, Dietary
Bran, Tablets
Buffered Mixture of Anion and Cation Exchange Resins

AUGUST 1985 AND NOVEMBER 1986 EDITION

Oxyquinoline
Acetanilide
Alcohol
Sabadilla Alkaloids
Benzalkonium Chloride
Alum, Ammonium and Alum, Potassium
Alum, Ammonium
Alum, Ammonium and Alum, Potassium
Aluminum Hydroxide
Aldioxa
Aluminum Hydroxide Gel
Aluminum Phosphate Gel
Aluminum Zirconium Tetrachlorohydrate Gly
Aluminum Zirconium Trichlorohydrate Gly
Glycine
Aminacrine Hydrochloride
Alum, Ammonium
Amyltriethylols, Secondary
Padimate A
Padimate A
Starch
Ammonium Solution, Strong
Coconut Oil Soap, Aqueous
Peruvian Balsam
Peruvian Balsam Oil
Sodium Bicarbonate
Sodium Borate
Bran
Bran
Anion and Cation Exchange Resins, Buffered

JANUARY 1984 EDITION

Calcium Carbaspirin
Candelillia Wax
Carrageenan (Degraded)
Carrageenan (Native)
Cascara Fluidextract Aromatic
Cascara Sagrada Bark
Chlorhydroxyquinoline
Chlorophyllins, Water-Soluble
Cloves, Ground
Codeine Alkaloid
Compound White Pine Syrup
Coriander, Ground
Corn Starch
D-Calcium Pantothenate
Dicalcium Phosphate Dihydrate
Dichlorodiphenyl Trichloroethane
DL-Methionine
Dodecaethyleneglycol Monolaurate
E. Coli Vaccines
Endothermic Hectorite
Epinephrine Hydrochloride (Racemic)
Escalol 506
Ethyl Alcohol
Extract White Pine Compound
Fluid Extract Ergot
Ginger, Ground
Glycerin, Anhydrous
Golder Seal
Hydrochloric Acid Diluted
Hydrocortisone Alcohol
Hydroxyethylcellulose
Infusion of Rose Petal
Iodochlorhydroxyquin
Karaya
L-Desoxyephedrine

AUGUST 1985 AND NOVEMBER 1986 EDITION

Carbaspirin Calcium
Wax, Candelilla
Carrageenan, Degraded
Carrageenan, Native
Cascara Fluidextract, Aromatic
Cascara Sagrada
Cloxyquin
Chlorophyllin Copper Complex
Clove
Codeine
White Pine Syrup, Compound
Coriander
Starch, Corn
Calcium Pantothenate
Calcium Phosphate, Dibasic
Chlorophenothane
Racemethionine
Dodecaethylene Glycol Monolaurate
E. Coli Vaccines
Hectorite
Epinephine Hydrochloride
Padimate A
Alcohol
White Pine Extract, Compound
Ergot, Fluidextract
Ginger, Jamaica
Glycerin
Hydrastis
Hydrochloric Acid, Diluted
Hydrocortisone
Hydroxyethyl Cellulose
Rose Petal, Infusion of
Clioquinol
Karaya Gum
Desoxyephedrine, L-

JANUARY 1984 EDITION

Lanolin Alcohol
Lanolin Anhydrous
Magnesium Aluminumsilicate
Mercurous Chloride
Mercury Chloride
Microporous Cellulose
Mineral Oil, Emulsified
Mustard Oil
Myrrh Tincture of
Opium Powder
Opium Tincture of
Orthophosphoric Acid
Para-Chloromercuriphenol
Para-Tertiary-Butyl-Meta-Cresol
Phenolphthalein, White
Phenyltolxamine Citrate
Phosphate, Disodium
Phosphate, Monosodium
Plantago Ovata Husks
Plantago Seed Husks
Plantago Seed, Blond
Poloxalkol
Polyoxyethylene Monolaurate
Polyvinylpyrrolidone
Potassium Alum
Potassium Aluminum Sulfate
Povidone-Iodine Complex
Proteins
Psyllium
Pyrethrin
Red Petrolatum
Released Carbon Dioxide
Sea Kelp
Sennosides A & B
Sodium Dihydrogen Phosphate

AUGUST 1985 AND NOVEMBER 1986 EDITION

Lanolin Alcohols
Lanolin, Anhydrous
Magnesium Aluminum Silicate
Calomel
Mercuric Chloride
Cellulose, Microporous
Mineral Oil
Allyl Isothiocyanate
Myrrh Tincture
Opium, Powdered
Opium Tincture
Phosphoric Acid
P-Chloromercuriphenol
P-T-Butyl-M-Cresol
Phenophthalein
Phenyltoloxamine Dihydrogen Citrate
Sodium Phosphate, Dibasic
Sodium Phosphate, Monobasic
Psyllium Husk
Psyllium Husk
Plantago Seed
Poloxamer 188
Polyoxyethylene Laurate
Povidone
Alum, Potassium
Alum, Potassium
Povidone-Iodine
Protein
Plantago Seed
Pyrethrins
Petrolatum, Red
Carbon Dioxide, Released
Kelp
Sennosides
Sodium Phosphate, Monobasic

JANUARY 1984 EDITION

Sodium Phosphate
Sodium Phosphate, Dibasic Anhydrous Reagent
Sodium Potassium Tartrate
Syrup of Pine Tar
Theophylline Anhydrous
Tincture of Impatiens Bi-Flora
Tincture of Iodine
Tricalcium Phosphate
Undecoylium Chlorideiodine Complex
Vitamin D
Vitamin D2
White Thyme Oil
Wintergreen Oil
Wool Alcohols
Zinc Pyrithione

JANUARY 1984, AUGUST 1985, AND NOVEMBER 1986

5-(3,3-Dimethyl-2-Norbornyliden)-3-Penten-2-One
Desoxyephedrine, L-
Isobutyl P-Aminobenzoate
Theophylline Anhydrous

JANUARY 1988 EDITION

Mercuric Chloride
Witch Hazel Water
Diphenhydramine Monocitrate

APRIL 1989 EDITION

Aluminum Carbonate Gel
Aluminum Aspirin
Calomel

AUGUST 1985 AND NOVEMBER 1986 EDITION

Sodium Phosphate, Dibasic
Sodium Phosphate, Dibasic
Potassium Sodium Tartrate
Pine Tar Syrup
Theophylline, Anhydrous
Impatiens Bi-Flora Tincture
Iodine Tincture
Calcium Phosphate, Tribasic
Undecoylium Chloride Iodine Complex
Cholecalciferol
Ergocalciferol
Thyme Oil, White
Methyl Salicylate
Lanolin Alcohols
Pyrithione Zinc

EDITIONS JANUARY 1988 EDITION

Bornelone
Levomethamphetamine
Isobutaben
Theophylline

APRIL 1989 EDITION

Calomel
Hamamelis Water NF XI
Diphenhydramine Citrate

JUNE 1990 EDITION

Basic Aluminum Carbonate Gel
Aspirin, Aluminum
Mercuric Chloride

JUNE 1990 EDITION

Carnauba Wax
Cocoa Butter Substitutes
Mercuric Chloride
Levomethamphetamine

DECEMBER 1991 EDITION

2-ethylhexyl salicylate
Aloe Vera
Aloe Vera Stabilized
Aloes
Chlorophyll
Boroglycerin glycerite
Diethanolamine P-methoxy-cinnamate
Ethylhexyl p-methoxycinnamate
Hamamelis Water NF XI
Oxyquinoline Sulfate
Pyrethins

DECEMBER 1991 EDITION

Wax, Carnauba
Hard Fat
Calomel
Desoxyephedrine, L-

SEPTEMBER 1994 EDITION

Octyl salicylate
Aloe
Aloe
Aloe
Chlorophyllin Copper Complex
Boroglycerin
Diethanolamine Methoxycinnamate
Octyl methoxycinnamate
Witch Hazel
Oxyquinoline
Pyrethrum Extract

PHARMACEUTICAL CHANGES

NOVEMBER 1991 PHARMUSE CHANGES

Under the Antimicrobial I Panel (AM), antiseptic, skin antiseptic, skin wound protectant, and skin wound cleanser was combined as first aid antiseptic.

SEPTEMBER 1994 PHARMUSE CHANGES

The Pharmaceutical use name for Boil Ointment has been changed to Boil Treatment.

INGREDIENT NAME ADDITIONS

INGREDIENT NAME ADDITIONS TO THE AUGUST 1985 AND NOVEMBER 1986 EDITIONS:

Dexbrompheniramine Maleate
Dexchlorpheniramine Maleate
Ipecac Tincture
Jojoba Oil
Nucleic Acids
Polycarbophil, Calcium

INGREDIENT NAME ADDITIONS TO THE AUGUST 1985 AND NOVEMBER 1986 EDITIONS (Cont'd):

Polysorbate 20
Polysorbate 60
Sulfanilamide
Sulfur (Paraffinic Hydrocarbons)
Vitamin B

INGREDIENT NAME ADDITIONS TO THE JANUARY 1988 EDITION

NONE

INGREDIENT NAME ADDITIONS TO THE APRIL 1989 EDITION

Diphenhydramine Citrate

INGREDIENT NAME ADDITIONS TO THE JUNE 1990 EDITION

Anise
Fennel
Golden Seal
Mandrake
Metacresol
Minerals
Pregnenolone

INGREDIENT NAME ADDITIONS TO THE JUNE 1990 EDITION

Pregnenolone acetate

Yohimbine

Yohimbinum

INGREDIENT NAME ADDITIONS TO THE DECEMBER 1991 EDITION

Alfalfa

Anise Oil

Arginine

Bearberry

Bone Marrow, Red

Buchu

Buchu, Extract

Calcium

Calcium Caseinate

Calcium Lactate

Chlorophyllin

Cholecalciferol

Choline

Cloxyquin

Cnicus Benedictus

Copper

Copper Gluconate

Corn Oil

Corn Syrup

Corn Silk, Extract

Cyanocobalamin

Cystine

Dextrose

Ferric Ammonium Citrate

Ferric Pyrophosphate

Ferrous Fumarate

Ferrous Gluconate

Ferrous Sulfate (Iron)

Flax Seed

INGREDIENT NAME ADDITIONS TO THE DECEMBER 1991 EDITION

Folic Acid
Histidine
Hydrastis Canadensis
Inositol
Isoleucine
Juniper, Extract
Lactose
Lecithin
Leucine
Liver Concentrate
Lysine
Magnesium
Malt
Maltodextrin
Manganese Citrate
Mannitol
Mono- and Di-Glycerides
Organic Vegetables
Pantothenic Acid
Papaya Enzymes
Phenacetin
Phenylalanine
Phosphorus
Phytolacca
Pineapple Enzymes
Poloxamer 407
Potassium Citrate
Riboflavin
Rice Polishings
Saccharin
Sea Minerals
Sesame Seed
Sodium
Sodium Caseinate
Soybean Protein

INGREDIENT NAME ADDITIONS TO THE DECEMBER 1991 EDITION

Soy Meal
Sucrose
Thiamine Mononitrate
Threonine
Tricalcium Phosphate
Tryptophan
Tyrosine
Uva Ursi, Extract
Valine
Vegetable
Vitamin A Acetate
Vitamin A Palmitate
Wheat Germ
Yeast

INGREDIENT NAME ADDITIONS TO THE SEPTEMBER 1994 EDITION

Amylase
Anise Seed
Aromatic Powder
Asafetida
Aspergillus Oryzae Enzymes
Bacillus Acidophilus
Barosma
Bean
Bearberry (Extract of Uva Ursi)
Bearberry Fluidextract (Extract of Bearberry)
Belladonna Leaves, Powdered Extract
Black Radish Powder
Blessed Thistle (Cnicus Benedictus)
Buchu Powdered Extract (Extract of Buchu)
Buckthorn
Calcium Gluconate
Capsicum, Fluid Extract of
Carbamide Peroxide in Anhydrous Glycerin

INGREDIENT NAME ADDITIONS TO THE SEPTEMBER 1994 EDITION

Carbon
Catechu, Tincture
Catnip
Chamomile Flowers
Cinnamon Oil
Cinnamon Tincture
Citrus Pectin
Couch Grass
Diastase
Diastase Malt
Dog Grass
Dog Grass Extract
Elecampane
Ether
Ethyl Nitrate
Fennel Acid
Formic Acid
Galega
Gentiana Lutea (Gentian)
Ginger
Horsetail
Huckleberry
Iron Ox Bile
Johnswort
Juniper Oil
Knotgrass
Lavender Compound, Tincture of
Linden
Lipase
Methylene Blue
Mycozyme
Myrrh, Fluid Extract of
Natural Estrogenic Hormone
Nettle
Nickel-Pectin

INGREDIENT NAME ADDITIONS TO THE SEPTEMBER 1994 EDITION

Nutmeg Oil (Oil of Nutmeg)
Nux Vomica Extract
Oil of Erigeron
Papaya, Natural
Peppermint
Peppermint Spirit
Phenylbenzimidazole Sulfonic Acid
Pipsissewa
Povidone-Vinylacetate Copolymers
Sage Oil
Saw Palmetto
Senna
Sodium Acetylsalicylate
Stem Bromelain
Strawberry
Sulfurated Oils of Turpentine
Trillium
Triticum
Woodruff